Testimony

STATEMENT OF
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DEPARTMENT OF DEFENSE
BEFORE THE
SENATE ARMED SERVICES COMMITTEE
ON
DEFENSE ANTHRAX VACCINE CONTRACTING

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Office of the Inspector General
Department of Defense

Mr. Chairman and Members of the Committee:

I appreciate the opportunity to be here today to discuss contracting issues related to the production of anthrax vaccine.

Congressional Request

On August 13, 1999, the Office of the Inspector General, DoD, received a request from Congressman Walter B. Jones for a review of the financial and contractual relationship between the Department of Defense and BioPort Corporation, the sole U.S. domestic source of Anthrax Vaccine Adsorbed (AVA). In his request letter, Congressman Jones noted that the General Accounting Office and Defense Contract Audit Agency had reported that BioPort was experiencing financial problems and having difficulty performing against Army contracts for AVA production. Congressman Jones expressed concern that "despite these serious questions regarding the overall viability of BioPort, the Federal government has chosen to more than double the value of the existing contract." The Congressman specifically requested that we review the renegotiation of the Army 1998 AVA production contract to provide relief to BioPort.

In response to this request, we conducted an audit between September 1999 and February 2000. We did not duplicate the extensive coverage of the anthrax vaccine program and related contracting issues by the General Accounting Office and Defense Contract Audit Agency. Each of those organizations had issued eight audit reports on these subjects by February 2000, and additional coverage was ongoing or planned. We focused primarily on determining the amount of relief provided to BioPort, the ways in which the relief was provided, whether the Department had legal authority to provide it, and whether it had alleviated the risk in the program.

Report D-2000-105, Contracting for Anthrax Vaccine, March 22, 2000

To comply with statutory and regulatory requirements for protecting contractor proprietary information, the full text version of our report is For Official Use Only and distribution is limited. Likewise, I am somewhat constrained today in terms of what details about the contractor's financial condition can be discussed in an open hearing.

I will begin with a brief recap of the history of AVA production. In 1970, the Food and Drug Administration granted

a license for producing AVA to the State of Michigan, which owned a vaccine manufacturing facility in Lansing. At the time, the primary market for AVA was commercial. The first of what would eventually be several Army contracts with the Michigan Biologic Products Institute or Michigan Department of Public Health was awarded in September 1988. In November 1996, the Food and Drug Administration inspected the production facility and in March 1997 issued a notice of intent to revoke its license. The facility was closed for major renovation from early 1998 until May 1999.

On September 4, 1998, BioPort Corporation purchased the Michigan Biologic Product Institute from the State of Michigan. The Michigan Biologic Products Institute entered into a novation agreement that transferred 3 open Army contracts to BioPort. A much larger AVA production contract was awarded by the Army to BioPort on September 15, 1998 to support the new DoD policy that all military personnel were to be inoculated against anthrax. The DoD expected to acquire about 8.7 million AVA doses for $29.4 million.

In June 1999, BioPort requested financial assistance from the Army to meet its immediate and short term cash flow deficit. Lacking Food and Drug Administration approval, BioPort had been

unable to make U.S. commercial sales. The firm also requested a decrease in the number of doses, an increase in the price per dose and a one-time advance cash payment.

The Army Contract Adjustment Board granted BioPort extraordinary contractual relief on the 1998 contract in a Memorandum of Decision, ACAB No. 1246, dated July 27, 1999. The Army provided extraordinary contractual relief to BioPort because the corporation had insufficient money to fund its operating expenses and satisfy its loan from the State of Michigan. Without extraordinary contractual relief, according to the Board, BioPort would not have been able to continue producing AVA, thus compromising the safety of military personnel and the national defense.

In accordance with the Board’s decision, the Army amended the September 1998 contract with BioPort and provided a net $24.1 million in relief, including an $18.7 million interest free advance payment. The number of doses in the contract options was reduced from 7.9 million to 4.6 million. The price was increased from $4.36 to $10.64 per dose for Option Year I and from $2.26 to $10.64 per dose for Option Year II.

We concluded that the Army had the legal authority to grant BioPort's request for extraordinary contractual relief. Public Law 85-804 has been interpreted to give the Government broad powers to grant the contractor whatever relief is necessary even when it may be caused by losses on non-Government work.

Despite the relief that was provided, during the period of our audit there was ample evidence of continued risk and of need for additional DoD financial assistance.

In December 1999, the Food and Drug Administration provided the results of its initial inspection of the BioPort facility and its review of BioPort's application, which is technically called a biologic establishment license application supplement. The inspection and review identified about 40 deficiencies of varying degrees of significance and today the application supplement remains unapproved, although we understand the DoD believes considerable progress has been made in addressing the deficiencies. We do not have current and first hand information on what impediments to approval remain or when it might be attained. Nor have we audited any contracting actions taken by the Department, subsequent to the measures taken to provide extraordinary relief in 1999. We are aware, however, that the Department is intensively managing the situation at BioPort,

including issues raised by the auditors. We strongly support the decision to establish a permanent Defense Contract Management Agency presence at the facility in Lansing. We also recently received a June 22, 2000 Defense Contract Audit Agency report indicating that BioPort's accounting system is now adequate, which resolves one of our concerns.

Conclusion

In summary, we determined that applicable laws and regulations allowed the Department to provide extraordinary relief to BioPort Corporation during late FY 1999, but significant risks continued. Because there appears to be no alternative U.S. domestic source, at least in the near term, the DoD anthrax vaccination policy is viable only if BioPort can bring its production facility up to Food and Drug Administration standards this year.

Beyond the current issues concerning AVA, however, we believe the DoD and Congress need to continue working toward a comprehensive, long term defensive strategy against the spectrum of potential chemical and biological warfare threats. Our work in DoD chemical and biological defense programs, as outlined in the attached list of reports and testimony, has indicated a wide

range of unresolved issues and difficult challenges in this broad area, whose importance to national security will surely continue to grow in the coming years.

This concludes my statement.

Inspector General, DoD, Reports on Chemical and Biological Defense

Report No. 94-154, Reliability of M-17 Series and M-40 Chemical Protective Masks, June 30, 1994 (Secret)

Report No. 95-021, Defense Hotline Allegations Regarding DoD Fielding of Chemical Protective Masks, November 2, 1994 (Secret)

Report No. 95-224, Army Chemical Protective Mask Requirements, June 8, 1995

Report No. 97-018, The Patriot Advanced Capability-3 Program, November 4, 1996

Report No. 97-102, Inventory Accuracy at the Defense Depot, Columbus, Ohio, February 27, 1997

Report No. 97-217, Chemical and Biological Defense Readiness, September 19, 1997 (Secret)

Report No. 98-174, Unit Chemical and Biological Defense Readiness Training, July 17, 1998

Report No. 99-045, Chemical and Biological Warfare Defense Resources in the U.S. Pacific Command, December 3, 1998 (Secret)

Report No. 99-061, M41 Protective Assessment Test System Capabilities, December 24, 1998

Report No. 99-102, Chemical and Biological Defense Resources in the U.S. European Command, March 4, 1999 (Secret)

IG Semiannual Report to Congress for the Period Ending March 31, 1999, Focus Area on Chemical and Biological Defense

Report No. D-2000-086, Assuring Condition and Inventory Accountability of Chemical Protective Suits, February 25, 2000

Report No. D-2000-105, Contracting for Anthrax Vaccine, March 22, 2000 (For Official Use Only)

Report No. D-2000-154, Statement of Donald Mancuso, Deputy Inspector General, DoD, Before the Subcommittee on National Security, Veterans Affairs and International Relations, House Committee on Government Reform, on Combating Terrorism: Individual Protective Equipment for U.S. Forces, Inventory and Quality Controls, June 24, 2000

All reports and testimony listed above that are not Classified or For Official Use Only are available on the Internet at www.dodig.mil. Also, a redacted version of some reports is available.